EXHIBIT AU

PROPOSED RULES
DEPARTMENT OF HEALTH AND HUMAN **SERVICES**
Health Care Financing Administration
42 CFR Parts 405 and 415
[BPD-2-P]
RIN 0938-AE91
Medicare Program; **Fee Schedule** for **Physicians' Services**
Wednesday, **June 5, 1991**

***25792** AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth a **fee schedule** for payment for **physicians' services** beginning January 1, 1992. Establishment of this **fee schedule** is required by section 6102(a) of the Omnibus Budget Reconciliation Act of 1989, as amended by the Omnibus Budget Reconciliation Act of 1990. This proposed rule explains which **services** would be included in the **fee schedule** and sets forth the formula for computing payment amounts. Application of transition rules during 1992 through 1995 is also described, as well as other adjustments to **fee schedule** payment amounts.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than **5** p.m. on August **5, 1991**.

ADDRESSES: Mail comments to the following address:

Health Care Financing Administration, Department of Health and Human **Services**, Attention: BPD-712-P, P.O. Box 26686, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments. In commenting, please refer to file code BPD-712-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309-G of the Department's offices at 200 Independence Avenue SW., Washington, DC., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-245-7890).

If you wish to submit comments on the information collection requirements contained in this proposed rule, you may submit comments to: Allison Herron, HCFA Desk Officer, Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503.

Copies: To order copies of the Federal Register containing this document, send your request to the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325. Specify the date of the issue requested and enclose a check or money

these services are furnished by physician staff so that we can evaluate both their frequency and the amount of payments made for them.

c. Drugs. The program currently pays for drugs furnished in physician's offices that are not self-administrable under the "incident to" provision set forth in section 1861(s)(2) of the Act. For the most part, drugs paid for under the "incident to" benefit consist of drugs furnished by injection or by infusion. This includes chemotherapy agents. Generally, carriers base payment for the drug on the physician's estimated cost of the drug using one of the wholesale price guides such as the Red Book. However, some carriers base payment on actual acquisition costs determined on the basis of carrier surveys.

We considered the following options for paying for drugs under the fee schedule:

Option 1--Establish a fee schedule payment amount for each drug.

Option 2--Bundle the payment for the drug into payment for the visit or consultation service.

Option 3--Make a separate payment for a drug and leave the pricing of the drug to each carrier.

Option 4--Make a separate payment for a drug but require a consistent method in pricing to be used by the carriers.

We believe that ultimately there should be a national fee schedule allowance for all "incident to" drugs. However, given the large number of different drugs and the myriad of dosage levels, we have decided that it is not practical for us to consider establishing a national drug fee schedule at this time. However, we will consider this issue in the future. Section 1848(j)(3) of the Act gives us the authority to specify that items and services be excluded from the fee schedule. Thus, we have decided to exclude the cost of drugs from the national fee schedule and to continue to pay for them under the current "reasonable charge" system. We believe, however, that there is a need for greater consistency in how drugs are paid for under the program and for this reason we have chosen Option 4. For purposes of payment for drugs furnished incident to a physician's service, the term "drug" includes those covered drugs and biologicals that cannot be self-administered. Also, we are proposing that we will instruct all carriers to base payment for drugs on 85 percent of the national average wholesale price of the drug (as published in the Red Book and similar price listings), but we welcome comments regarding the appropriate discount.

Medicare policy, since the beginning of the Medicare program, has been to base payment for "incident to" drugs on the estimated acquisition costs. However, based on studies by the Office of the Inspector General (OIG) ("Changes to the Medicaid Prescription Drug Program Could Save Millions" (ACN 06-40216) and "Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program" (A-06-89-00037)) and other information, we believe that the Red Book and other wholesale price guides substantially overstate the true cost of drugs. The OIG reports indicate that pharmacies are getting an average discount of 15.9 percent off the published wholesale price. We have no reason to believe prices paid by physicians are any higher than pharmacies pay. Moreover, we are proposing for very high volume drugs that payment for the drug would be limited to the lower of the estimated acquisition cost for the drug as determined by us and specified in instructions to carriers or 85 percent of the national average wholesale price for the drug. The listing of the high volume drugs and payment limits for them will be included in the Medicare Carriers Manual.

We propose this payment policy for drugs that are incident to physician services under the authority of section 1842(b)(8) of the Act, which permits us to establish limits on charges based on inherent reasonableness. This provision of the law is implemented in regulations at § 405.502(g). The regulations permit us to establish a limit on the reasonable charge for an item or service if we determine that charge is grossly lower than or in excess of acquisition or production costs for the item or service (§ 405.502(g)(1)(vi)).

As indicated in our previous discussion, we base the payment ***25801** limitation for drugs on the findings of the OIG with regard to the discounting of drugs to pharmacies below the average wholesale price. We believe that physicians also have the opportunity to achieve these discounts from drug manufacturers and wholesalers, since drug sales are dependent upon the drugs a physician prescribes for his or her patients, not only for administration in the physician's office, but also for self-administration or administration in a hospital or other institution. Therefore, we believe that physicians are in an excellent position to demand discounts such as those that the OIG study finds are typically given to pharmacies.

We believe that the impact of this special charge on physician services will be minimal because the drugs to which this provision applies are incidental to the physician's professional services and, to be covered, the law requires that they be "* * * of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills." (section 1861(s)(2)(A) of the Act). Since the physician has great leverage with the entity from which he or she purchases drugs to acquire a significant discount for the drug, we do not anticipate that there will be an adverse effect upon quality, access, beneficiary liability, assignment rates, reasonable charge reductions on unassigned claims, and participation rates of physicians.

Currently, the program usually pays a separate charge for an injection by a physician or by other health personnel incident to a physician's service (see the Medicare Carriers Manual, section 5202). If the customary practice in the area is not to charge for the injection furnished in the course of a visit, no payment is currently made for the injection. If the purpose of a visit is only to receive an injection, payment for the injection is made and payment for the visit is not allowed. If special skills are needed for the injection, payment is made based on the reasonable charge practices in the area (the Medicare Carriers Manual, section 5202.2). We propose to change this current policy with implementation of the fee schedule. In general, when a physician provides a visit or other service to a beneficiary and, in the course of that encounter, the beneficiary also receives a subcutaneous, intramuscular, intravenous, or intra-arterial injection, no additional payment would be made for the administration of the injection. The drug would be paid separately as discussed above. Payment for both the cost of non-drug supplies and administration of the drug would be included in the payment for the visit or other service. Generally, if a beneficiary receives an injection, we expect that the physician would bill for a minimal office visit. We believe it is rare when a beneficiary who needs an injection does not also need at least a minimal level of involvement of a physician as part of the service.

In those unusual circumstances in which no evaluation and management service or other service is furnished to the beneficiary and the physician bills only for the injection (for example, a routine B12 injection for pernicious anemia), payment for the injection would be based on the RVUs for the applicable injection code.

This general policy would also apply to subcutaneous, intramuscular, intravenous, and intra-arterial injections for purposes of cancer chemotherapy. However, infusion of cancer chemotherapy drugs (CPT 96410, 96412, 96414, 96422, 96423, 96425) and administration of cancer chemotherapeutic agents into specialized body cavities (CPT 96440, 96445, 96450) are considered to be procedures, not injections, for purposes of this policy. Therefore, we propose to pay separately for chemotherapy infusions and chemotherapy administration into specialized body cavities regardless of whether these services occur during a visit, infusion of another drug, or while another service is furnished. We would also pay separately for drugs and chemotherapy agents as discussed in this section.

Of course, when cancer chemotherapy is administered to a hospital patient by personnel other than those practitioners authorized to bill separately under Part B for their professional services (that is, a physician, PA, NM, CRNA, or CP), the chemotherapy administration is a hospital service and cannot be billed by a practitioner. Chemotherapy administration can be billed by a physician only when it is furnished by the physician or staff outside a hospital setting. Chemotherapy furnished by the physician's staff may be paid by Medicare only when the requirements for coverage as "incident to a physician's service" contained in Medicare Carriers Manual, section 2050 are met. The proposed regulations for the payment of drugs beginning January 1, 1992 appear in new § 415.34.

B. Formula for Computing Payment Amounts

Section 1848(a) of the Act specifies that payment for Medicare physicians' services must be based on the lesser of the actual charge or the payment amount computed under the fee schedule. Although the law refers to the fee schedule values as "payment amounts," in fact under the statutory formula the amount paid to a physician (often referred to as the "allowed charge") would be 80 percent of the actual charge or 80 percent of the fee schedule payment amount, whichever was less. The beneficiary is required to pay the remaining 20 percent. Throughout the preamble of this proposed rule and in the proposed regulation itself, we have used the terms "fee schedule payment amount," "payment amount," and "payment" as used in the statute to include the amounts for which both the beneficiary and Medicare are responsible.

Under the formula set forth in section 1848(b)(1) of the Act, payment amounts for particular services under the physician fee schedule would be computed as the product of three factors: (1) A relative value for the service, (2) the GAF for the fee schedule area, and (3) a nationally uniform dollar CF. (Although we generally describe a single nationally uniform CF, different CFs for surgical services and other services may be established as part of the Medicare volume performance standards (MVPS) and annual update process. (See section IV.E.4. for further explanation.) This general formula can be expressed as:

Payments=RVUtsxGAFtsaxCF

where

RVUt=Total relative value units for the service

GAFt=Total geographic adjustment factor for the fee schedule area

CF=Uniform national conversion factor

42 CFR § 415.32

§ 415.32 Payment for services and supplies incident to a physician's service.

(a) Medical supplies. (1) Except as otherwise specified in this paragraph, office medical supplies are considered to be part of a physician's practice expense and payment for them is included in the practice expense portion of the payment to the physician for the medical or surgical service to which they are incidental.

(2) If physician services of the type routinely furnished in provider settings are furnishing in a physician's office, separate payment may be made for certain supplies furnished incident to that physician service. For the purpose of this paragraph, provider settings are limited to the following settings:

(i) Hospital inpatient and outpatient departments.

(ii) Ambulatory surgical centers.

(3) HCFA establishes a list of services routinely furnished in a provider setting, based on the services being furnished 50 percent or more of the time in a provider setting.

(4) HCFA establishes the list of supplies for which additional payment ***25860** may be made. Payment is only made for medical supplies when these items are disposable and are dedicated to the use of a single beneficiary.

(5) The fee schedule amount for a year is based on estimated average allowed charges for 1991 for the supplies, adjusted by the CF update described in § 415.30 without a geographic adjustment for practice costs.

(b) Services of nonphysicians that are incident to a physician's service. Services of nonphysicians that are covered as incident to a physician's service are paid as if the physician had personally furnished the service.

42 CFR § 415.34

§ 415.34 Payment for drugs incident to a physician's service.

(a) General. Payment for drugs incident to a physician's service is not made under the fee schedule.

(b) Payment rule. Except as specified in paragraph (d) of this section, payment for drugs furnished incident to a physician's service is limited to 85 percent of the national average wholesale price of the drug as determined by HCFA.

(c) Payment for high volume drugs. HCFA identifies high volume drugs or high cost drugs and establishes payment limits for them in instructions to carriers. Payment for these drugs is limited to the lower of the estimated acquisition cost for the drug as determined by HCFA and specified in instructions or 85 percent of the national average wholesale price for the drug.

42 CFR § 415.36

§ 415.36 Coding and ancillary policies.

(a) General rule. HCFA establishes uniform national definitions of services, codes to

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termined in accordance with [illegible].511, in the carrier's service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.

.01 Source:

As adopted, 46 F.R. 42669 (Aug. 24, 1981, effective for bills submitted or requests for payment made after Mar. 1981), and as amended at 51 F.R. 41332 (Nov. 14, 1986, effective Dec. 15, 1986) (cross-reference change only).

[¶ 19,117]

§ 405.517 Payment for drugs that are not paid on a cost or prospective payment basis.

(a) *Applicability.* Payment for a drug that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies includes a drug furnished incident to a physician's service and a drug furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter.

(b) *Methodology.* Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage.

(c) *Multiple-Source drugs.* For multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

.01 Source:

As adopted, 56 F.R. 59501 (Nov. 25, 1991, effective Jan. 1, 1992, applicable to services furnished beginning Jan. 1, 1992).

[¶ 19,120]

§ 405.520 Reimbursement for services of interns, residents and supervising physicians; general.

(a) Under the health insurance program, almost all the aged have protection against hospital expenses, and the great majority also have protection against [illegible] health insurance coverage [illegible] vide a substantial measure o[illegible] ficiaries in selecting hospitals [illegible] of their choice. Whatever the c[illegible] ciaries, as insured patients, are to b[illegible] ded the same status as other insured and paying patients in regard to the hospital and medical care they are provided.

(b) Many beneficiaries will choose to receive the care they need from hospitals with approved graduate medical education programs and from other institutions where services of interns and residents are provided. Many will receive care in these hospitals as patients of physicians who, in turn, will involve interns and residents in the care of their patients. The basis for reimbursement for such services by interns and residents is different from that applicable to such physicians' services.

.01 Source:

As adopted, 32 F.R. 12599 (Aug. 31, 1967); recodified as 42 CFR 405.520 (formerly 20 CFR 405.520) at 42 F.R. 52826 (Sept. 30, 1977, effective Oct. 1, 1977).

[¶ 19,121]

§ 405.521 Services of attending physicians supervising interns and residents.

(a) *Basic rules.* (1) Attending physicians' services furnished to beneficiaries in a teaching setting are covered under Medicare Part B; and

(2) The payment for these services is on the same fee schedule basis as other physician services except in those hospitals that have elected cost reimbursement under paragraph (d)(2) of this section.

(b) *Physician direction requirements.* (1) Payment on the basis of the physician fee schedule applies to the professional services furnished to a beneficiary by the attending physician when the attending physician furnishes personal and identifiable direction to interns or residents who are participating in the care of the patient.

(2) In the case of major surgical procedures and other complex and dangerous procedures or situations, the attending physician must personally supervise the residents and interns whom the physician involves in the care of the patients.

(3) Part B payment may be made for the services of an attending physician who involves residents and interns in the care of a patient only if the physician assumes and fulfills the same responsibilities for this patient as for other paying patients.

(4) The carrying out by the physician of these responsibilities would be demonstrated

M.P 2-5

Q: Should carriers provide separate payment outside of the physician fee schedule for surgical dressings, splints, casts and other devices used to treat fractures and dislocations when billed by physicians?

A: Do not make separate payment for surgical dressings billed by physician. Surgical dressings are generally considered "incident to" supplies typically found in physicians' offices and not separately billable. Although these items have a separate coverage category, Medicare has generally paid for these items in the past under the "incident to" provision. Because Medicare has not paid for these items separately in the past and the practice expense RVU under the physician fee schedule is based on the historical average allowed charge, their cost is included in the fee schedule payment.

However, pay separately on a reasonable charge basis for splints, casts, and other devices used to treat fractures and dislocations billed by physicians. There are separate "A" codes for these items. Because these items have a separate coverage provision and because we do not believe they have been paid historically under the "incident to" provision, they generally have not been included in physicians' historical charges. Consequently, the practice expense RVUs do not include the cost of these items.

HCFA *Memorandum* BPO-001, PPR-91-34.

[¶ 3421] Drugs

Drugs furnished incident to a physician's services were included in the physician's payment under the reasonable charge system but are not included in the physician's fee schedule payment (see ¶ 3126). Instead, Medicare will pay for them separately. [Reg. § 414.36.]

Medicare pays for covered drugs at the lower of (1) the estimated acquisition cost of the drug or (2) the national average wholesale price of the drug (as published in the Red Book and similar price listings). If a drug has multiple sources, the median of the national wholesale generic prices is used to determine the national average. Estimated acquisition costs will be determined through provider surveys of actual invoice prices. [Reg. § 405.517.]

The foregoing payment policy for drugs is applicable to *all* drugs furnished to Medicare beneficiaries that are not "paid for on a cost or prospective payment basis." Drugs furnished incident to a physician's services fall within this category. To be considered incident to a physician's services, a drug must be of a kind that is commonly furnished in a physician's office and is commonly either rendered without charge or included in the physician's bill. [Soc. Sec. Act § 1861(s)(2).] Also subject to the payment policy described above are drugs provided by independent end-stage renal disease facilities. [Reg. § 405.517.]

Injections

When a physician provides a visit or other service, and at the same time gives the patient a subcutaneous, intramuscular, intravenous, or intra-arterial injection, no additional payment is made for the administration of the injection. Payment is made separately for the drug injected, but the cost of the other supplies and the administration of the drug is included in the payment for the visit or other service (see ¶ 3445.15). [56 FR 59525 (GUIDE Extra Edition No. 678).]

If the physician bills for just the injection and not a visit, payment for the injection would be based on the applicable injection code (see .20, below). Infusions of cancer chemotherapy drugs in the areas of the body described above are considered to be procedures and not injections. Thus, payment can be made for both a visit and the infusion. Medicare will pay physicians for these infusions only when furnished outside the hospital setting. [56 FR 59525.]

Although allergy testing services are paid under the fee schedule, antigens are not included in the law's definition of physicians' services subject to fee schedule payment. Accordingly, these services continue to be paid based upon reasonable charges. [MCM § 15068.] Similarly, the administration or injection of pneumococcal, influenza, or hepatitis B vaccine is not paid under the fee schedule. [MCM § 15002.]

EXHIBIT AW

ugust 1, 1997

REQUIREMENTS

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That the provisions
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BALANCED BUDGET ACT OF 1997

For Legislative History of Act, see Report for P.L. 105–33 in U.S.C.C. & A.N. Legislative History Section.

For Signing Statement of Act, see Statement for P.L. 105–33 in U.S.C.C. & A.N. Legislative History Section (U.S.C.C. & A.N. No. 8).

An Act to provide for reconciliation pursuant to subsections (b)(1) and (c) of section 105 of the concurrent resolution on the budget for fiscal year 1998.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Balanced Bux Act of 1997.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Balanced Budget Act of 1997".

SEC. 2. TABLE OF TITLES.

This Act is organized into titles as follows:

TITLE I—FOOD STAMP PROVISIONS

SEC. 1001. EXEMPTION.

Section 6(o) of the Food Stamp Act of 1977 (7 U.S.C. 2015(o)) is amended—

(1) in paragraph (2)(D), by striking "or (5)" and inserting "(5), or (6)";

(2) by redesignating paragraph (6) as paragraph (7); and

(3) by inserting after paragraph (5) the following:

"(6) 15-PERCENT EXEMPTION.—

"(A) DEFINITIONS.—In this paragraph:

"(i) CASELOAD.—The term 'caseload' means the average monthly number of individuals receiving food stamps during the 12-month period ending the preceding June 30.

"(ii) COVERED INDIVIDUAL.—The term 'covered individual' means a food stamp recipient, or an individual denied eligibility for food stamp benefits solely due to paragraph (2), who—

"(I) is not eligible for an exception under paragraph (3);

"(II) does not reside in an area covered by a waiver granted under paragraph (4);

*Note: This is a hand enrollment pursuant to Public Law 105–32.

part may implement changes relating to requirements for the submission of a claim for clinical diagnostic laboratory tests.

(4) USE OF INTERIM POLICIES.—After the date the Secretary first implements such national policies, the Secretary shall permit any carrier to develop and implement interim policies of the type described in paragraph (1), in accordance with guidelines established by the Secretary, in cases in which a uniform national policy has not been established under this subsection and there is a demonstrated need for a policy to respond to aberrant utilization or provision of unnecessary tests. Except as the Secretary specifically permits, no policy shall be implemented under this paragraph for a period of longer than 2 years.

(5) INTERIM NATIONAL POLICIES.—After the date the Secretary first designates regional carriers under subsection (a), the Secretary shall establish a process under which designated carriers can collectively develop and implement interim national policies of the type described in paragraph (1). No such policy shall be implemented under this paragraph for a period of longer than 2 years.

(6) BIENNIAL REVIEW PROCESS.—Not less often than once every 2 years, the Secretary shall solicit and review comments regarding changes in the national policies established under this subsection. As part of such biennial review process, the Secretary shall specifically review and consider whether to incorporate or supersede interim policies developed under paragraph (4) or (5). Based upon such review, the Secretary may provide for appropriate changes in the national policies previously adopted under this subsection.

(7) REQUIREMENT AND NOTICE.—The Secretary shall ensure that any policies adopted under paragraph (3), (4), or (5) shall apply to all laboratory claims payable under part B of title XVIII of the Social Security Act, and shall provide for advance notice to interested parties and a 45-day period in which such parties may submit comments on the proposed change.

(c) INCLUSION OF LABORATORY REPRESENTATIVE ON CARRIER ADVISORY COMMITTEES.—The Secretary shall direct that any advisory committee established by a carrier to advise such carrier with respect to coverage and administrative policies under part B of title XVIII of the Social Security Act shall include an individual to represent the independent clinical laboratories and such other laboratories as the Secretary deems appropriate. The Secretary shall consider recommendations from national and local organizations that represent independent clinical laboratories in such selection.

SEC. 4555. UPDATES FOR AMBULATORY SURGICAL SERVICES.

Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended by inserting at the end the following new sentence: "In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.".

SEC. 4556. REIMBURSEMENT FOR DRUGS AND BIOLOGICALS.

(a) IN GENERAL.—Section 1842 (42 U.S.C. 1395u) is amended by inserting after subsection (n) the following new subsection:

"(o)(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug

or biological for which p
and the drug or biologic
payment basis as otherw
payable for the drug or
average wholesale price.

"(2) If payment for a
pharmacy approved to di
part, the Secretary may
deductible and coinsurance

(b) CONFORMING AME
1395l(a)(1)), as amended
amended—

(1) by striking "an

(2) by striking t
the following: ", and
not paid on a cost or
provided in this part
in subparagraph (B)),
of the lesser of the
established in section

(c) STUDY AND REPOR
Services shall study the
drugs and biologicals of
and shall report to the Co
merce of the House of
Finance of the Senate t
July 1, 1999.

(d) EFFECTIVE DATE.—
(a) and (b) shall apply t
after January 1, 1998.

SEC. 4557. COVERAGE O
CHEMOTHERA

(a) IN GENERAL.—Se
as amended by sections 41

(1) by striking "a

(2) by inserting a
subparagraph:

"(T) an oral drug
and Drug Administra
emetic used as part of
if the drug is admini
by a physician)—

"(i) for use in
after the time o
chemotherapeutic

"(ii) as a full
which would oth

(b) EFFECTIVE DATE.—
(a) shall apply to items ar
1, 1998.

SEC. 4558. RENAL DIALYSIS-

(a) AUDITING OF COS
for 1996, the Secretary sha
provider at least once ever

(b) IMPLEMENTATION
of Health and Human S

or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to 95 percent of the average wholesale price.

"(2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy.".

(b) CONFORMING AMENDMENT.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)), as amended by sections 4315(b) and 4531(b)(1), is amended—

(1) by striking "and (R)" and inserting "(R)"; and

(2) by striking the semicolon at the end and inserting the following: ", and (S) with respect to drugs and biologicals not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o);".

(c) STUDY AND REPORT.—The Secretary of Health and Human Services shall study the effect on the average wholesale price of drugs and biologicals of the amendments made by subsection (a) and shall report to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate the result of such study not later than July 1, 1999. 42 USC 1395u note.

(d) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall apply to drugs and biologicals furnished on or after January 1, 1998. 42 USC 1395l note.

SEC. 4557. COVERAGE OF ORAL ANTI-NAUSEA DRUGS UNDER CHEMOTHERAPEUTIC REGIMEN.

(a) IN GENERAL.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by sections 4104 and 4105, is amended—

(1) by striking "and" at the end of subparagraph (R); and

(2) by inserting after subparagraph (S) the following new subparagraph:

"(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)—

"(i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and

"(ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to items and services furnished on or after January 1, 1998. 42 USC 1395x note.

SEC. 4558. RENAL DIALYSIS-RELATED SERVICES. 42 USC 1395rr note.

(a) AUDITING OF COST REPORTS.—Beginning with cost reports for 1996, the Secretary shall audit cost reports of each renal dialysis provider at least once every 3 years.

(b) IMPLEMENTATION OF QUALITY STANDARDS.—The Secretary of Health and Human Services shall develop, by not later than

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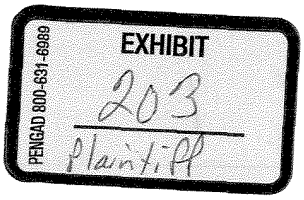
Health Care Financing Administration
Office of Legislation

FAX COVER SHEET

March 2, 1998

FAX TO:	ROB VITO
FAX #:	215-596-6987
PHONE #:	
ORGANIZATION:	OIG
FROM:	MAUREEN ADOLPH FURLETTI
FAX #:	(202) 690-8168
PHONE#:	(202) 690-5507
RE:	MEDICARE OVERPAYMENT FOR DRUGS
NOTE:	Attached is last year's language from the President's budget bill. The administration is again putting forth this proposal in the FY 1999 budget package. Also attached is a short summary/rationale from last year's budget package. Let me know if you need further info.

PAGES (INCLUDING COVER): 5



PROPOSALS

(a) IN GENERAL.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended to read as follows:

"(o) ELIMINATION OF MARK-UP FOR DRUGS AND BIOLOGICALS.—

"(1) IN GENERAL.—If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological shall be the lowest of--

"(A) the physician's, supplier's, or other person's actual acquisition cost, as specified in paragraph (2),

"(B) the average wholesale price, as specified by the Secretary,

"(C) the median actual acquisition cost of all claims for the drug or biological for the 12-month period beginning July 1, 1998, adjusted annually and effective on January 1 of each year beginning with 2000, and

"(D) the amount otherwise determined under this part,

less the applicable deductible and coinsurance amounts.

"(2) ACTUAL ACQUISITION COST.--The actual acquisition cost is the physician's, supplier's or other person's cost

one or more individuals in violation of subparagraph (B), the Secretary may apply sanctions against that physician, supplier, or other person in accordance with subsection (j)(2).

"(4) DISPENSING FEE FOR PHARMACIES.—The Secretary may pay a reasonable dispensing fee (less the applicable deductible and insurance amounts) to a licensed pharmacy approved to dispense drugs or biologicals under this part, if payment for a drug or biological is made to the pharmacy.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) apply to drugs and biologicals furnished on or after January 1, 1998.

SEC. 11237. PAYMENTS TO PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, AND CLINICAL NURSE SPECIALISTS.

(a) COVERAGE IN HOME AND AMBULATORY SETTINGS IN WHICH A FACILITY OR PROVIDER FEE IS NOT BILLED FOR PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, AND CLINICAL NURSE SPECIALISTS.—Section 1861(s)(2)(K) (42 U.S.C. 1395x(s)(2)(K)) is amended—

(1) in clause (i)—

(A) by striking "or" at the end of subclause (II), and

(B) by inserting "or (IV) in a home or ambulatory setting in which a facility or provider fee is not

regardless of whether the primary surgeon elects to use an assistant-at-surgery. **This proposal achieves about $0.4 billion in savings over five years.**

- Create Incentives to Control High-Volume Inpatient Physician Services. Urban Institute research has found wide variation among hospitals in the volume of physician services per admission, even after adjusting for case severity, teaching hospital status, and disproportionate-share status. This proposal would create incentives to encourage physicians with high-volume inpatient practice styles to become more efficient. Effective January 1, 2000, this proposal would limit payments to groups of physicians practicing in hospitals whose volume and intensity of services per admission exceeded 125 percent of the national median for urban hospitals (125 percent in 2002 and thereafter) and 140 percent for rural hospitals. For each physician practicing in hospitals above those limits, 15 percent of each payment would be withheld during the year. If the physicians collaborate to efficiently manage the volume and intensity of the services they provide during the year, the physicians would receive the withheld payments, plus interest at the end of the year. **This proposal achieves about $2 billion in savings over five years.**

- Direct Payment to Physician Assistants, Nurse Practitioners, and Clinical Nurse Specialists in Home and Ambulatory Care Settings. Medicare currently pays for services provided by physician assistants, nurse practitioners and clinical nurse specialists -- but only in limited settings (primarily rural areas and nursing facilities). Effective January 1, 1998, this proposal would expand coverage to include home and ambulatory care settings in which a separate facility or provider fee is not charged. **The five-year investment for this proposal is about $0.6 billion.**

- Pay Based on Acquisition Costs Subject to a Limit for Outpatient Drugs Prescribed in Physicians' Offices. While Medicare does not have an expansive outpatient drug benefit, it does cover certain kinds of outpatient drugs, e.g., certain specific drugs that are used with home infusion or inhalation equipment and drugs that are prescribed for dialysis and organ transplant patients. Medicare typically pays for these drugs based on the charge submitted by providers, usually physicians or pharmacies. The HHS IG estimates that Medicare currently pays 15 to 30 percent more than what the provider paid for the drug. Effective January 1, 1998, this proposal would eliminate that mark-up by basing Medicare's payment on the provider's acquisition cost of the drug. As a back-stop, payments for a particular drug would not be allowed to exceed the national median cost of that drug. **This policy achieves about $0.8 billion in savings over five years.**

- Improve Access to Chiropractic Services. If a beneficiary chooses to see a chiropractor for Medicare-covered services, Medicare currently requires that the beneficiary get an x-ray demonstrating spinal subluxation (i.e., misalignment) before beginning chiropractic spinal manipulation services. In some cases, this x-ray requirement may hinder a beneficiary's access to chiropractic services. Effective January 1, 1998, this proposal

EXHIBIT AY

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL	: MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	: CIVIL ACTION:
PRICE LITIGATION	: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO	:
U.S. ex rel. Ven-a-Care of	: Judge Patti B. Saris
the Florida Keys, Inc. v.	:
Abbott Laboratories, Inc.,	: Chief Magistrate
No. 06-CV-11337-PBS	: Judge Marianne B.
	Bowler

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

STATE OF ALABAMA,	:
Plaintiff,	:
vs.	: Case No.: CV-05-219
ABBOTT LABORATORIES, INC.,	: Judge Charles Price
et al.,	:
Defendants.	:

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acquisition costs. So while I don't have any reason to think this isn't the proposal, if you woke me up and said what did you propose, I would have said actual acquisition cost.

Q. Okay. What would be the process for developing this sort of a budget proposal within the Administration in 1997? To put it more sharply, if this is the President's 1997 budget, who probably wrote that?

A. I don't know. It wouldn't have been me.

Q. Some poor underpaid staffer in the bowels of the Executive Office building?

A. The budget language, legislative language was put together in a variety of ways. Sometimes it was languages that had been drafted on the Hill from previous years. Sometimes it was language that had been drafted by an agency. Sometimes OMB asked the agency to draft -- here is what the Administration wants to do, agency, you draft the legislative language. Sometimes it would have been drafted within the Office of

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Management and Budget.

So it just depended. And I don't know how this came to be drafted.

Q. Who would be responsible, if anybody, for collecting all of this legislative language together and putting together the formal proposed budget of the Administration in 1997?

A. It would have been an office within the Office of Management and Budget.

Q. Do you know who the individual would have been in 1997, who was in charge of that office?

A. No. I really don't.

Q. What I'm trying to get to is, if I were going to try to find a copy of the proposed budgets and the people who worked on it, granted ten years ago, do you have any suggestions about how you would go about doing that?

A. Well, the budget document is published by the Government Printing Office. Every year when it's submitted, the President goes up and gives the State of the Union, which includes a

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budget message and the next day stacks of these things go out, and there is a always a big picture on the front of USA Today, stacks of budgets and how big is it this year. So I'm sure they are all on file with the Government Printing Office.

Q. Okay. In terms of determining the process by which -- I almost slipped into what your successor said -- the process by which the sausage was made, how would I go about doing that?

A. Meaning, where did specific language come from? Gosh, I don't know. The budget document, there is about six different volumes of the budget document, and some of them are just tables and some of them are legislative language. And I believe -- wait a minute. You know, I may be misremembering this. Because there's five or six volumes of the budget and as I said, they are printed by the Government Printing Office and they would be in any library, any large library in town. You might have them here at your law

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firm. They are bound and all that.

Legislative language is somewhat different. I believe there are even times when the Administration doesn't send legislative language, just relies on the verbiage in the budget document.

Q. And leaves it to Congress to draft it?

A. Leaves it to Congress to draft it. Because that's -- they have full-time staff that draft legislation. So in trying help you determine what process, I just, I don't really know. It would depend on the year and probably if I were looking for it I would go to the Congressional Budget Committee, because they would have been the recipient of -- if the Administration did do a draft of the legislative proposals to enact its budget, probably it would have gone to the committee on the budget in either House.

Q. So if this is the proposed language submitted by the President in 1997, there's a Congressional Budget Committee that would have

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received this proposed language as what the President wanted to be enacted?
A. I believe there would be that, in the House and the Senate.
Q. And in this instance, what was enacted, was payment at 95 percent of AWP; right?
A. For fiscal year '98, yes.
Q. Yes, ma'am. If you turn to the very last page of this document, the one page of the fax entitled, Medicare Savings and Investments Proposals in the President's Fiscal Year 1998 Budget. It's only one page out of a document that's at least nine pages long. It seems to summarize and then give a financial impact for various provisions in the budget.
Do you recognize this?
A. No.
Q. Have you ever seen anything -- did you ever see anything like it when you were at OMB or HCFA?
A. Yes.
Q. When you saw things like it, what was

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the context in which documents like this were prepared or used?
MS. YAVELBERG: Objection; form.
A. Well, I don't recall seeing this kind of thing at HCFA, but at OMB when the President's Budget was submitted to Congress, normally there would be some shorter documents in addition to the big stack of actual, you know, budget documents that I mentioned, that would give a more plain English description of things.
Q. I would like to direct your attention on this particular document to the second paragraph from the bottom, which is the paragraph entitled, Pay based on acquisition costs, subject to a limit for outpatient drugs prescribed in the physician's office.
You'll see that that paragraph first goes to state that Medicare does not have an expansive outpatient drug benefit. It does describe the limited circumstances under which Medicare does pay for outpatient drugs; correct?
A. Yes.

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Q. And those are some of the contexts which we've described before; home infusion, inhalation equipment, some drugs prescribed for dialysis; correct?
A. Yes.
Q. And home infusion, do you understand that to be referring to the infusion of drugs in the home that could be paid for if done with, under the Durable Medical Equipment Benefit?
MS. YAVELBERG: Objection; form.
A. Now I do. As I told you, that wasn't something I ever spent much time on. But, yeah, I think that's basically right.
Q. The paragraph then goes on to describe how Medicare typically pays for the drugs based on the charge submitted by the providers, and talks about the Office of Inspector General estimating Medicare is paying more than what providers are actually acquiring the drugs at; correct?
MS. YAVELBERG: Objection; form.
A. That's what this says, but that

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language seems odd to me.
Q. And then according to this summary, it indicates that the President's proposal for an acquisition cost methodology for paying it would eliminate the mark-up by basing Medicare's payment on the provider's acquisition cost of the drug.
Is that consistent with your recollection of what it was that the President proposed for the Fiscal Year 1998 Budget?
A. That sentence, yes, this proposal would eliminate that mark-up and base Medicare's payments on the provider's acquisition costs. Yes, I remember that. What seems odd to me is Medicare typically pays for these drugs based on the charge submitted by providers. I would have said AWP, but --
Q. You'll recall the program memorandum we looked at earlier indicated that it was the lower of the charge or the AWP; right?
A. Well, no. I thought it said estimated acquisition cost based on the --

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MS. YAVELBERG: Objection; form.
A. That these members of Congress were concerned about the plan that had been announced in the letter to Chairman Bliley and in the letter that I sent to other members of Congress to provide the additional source of data to the carriers on AWP.
Q. If you look at the bottom of the first page, the Congressman writes, quote: The Congress in 1997 instructed the department to base reimbursement for drugs on 95 percent of AWP; a term widely understood and indeed defined by department manuals to reference amounts reflect in specified publications.
First of all, is that a correct statement of what Congress did in 1997?
MS. YAVELBERG: Objection to form.
A. Yes.
Q. And the very first letter -- sentence of the letter is that the primary responsibility of the Medicare program must be to ensure continuity of care to beneficiaries. That's a

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true statement; correct?
A. I believe it's a very important responsibility to the Medicare program, to ensure care to beneficiaries.
Q. The Congressman complained that the data that -- this is the third paragraph -- the data, referring to the data collected by the Department of Justice, do not take into account the fact that oncologists are chronically underpaid for their drug administration services in treating cancer patients. In fact, it is widely recognized, including in your letter announcing the plan to reduce reimbursement. Did you understand that to be a concern, one of the concerns of these 91 members of Congress?
A. I understood -- I understand that that's what this letter says. I did not agree that it was widely recognized. Because I remember being surprised when my staff told me that they thought it was something we needed to look at.
Q. And after receiving this letter, did

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the department change its approach to disseminating the DOJ data to exclude chemotherapy drugs?
A. Well, I changed --
Q. You changed it?
A. -- my approach, yes.
Q. I hand you what I'll mark as Exhibit Abbott 221.
(Exhibit Abbott 221 was marked for identification.)
BY MR. COOK:
Q. For the record, this is a November 17, 2000 program memorandum entitled Source of Average Wholesale Price Data for Pricing Drugs and Biologicals Covered by the Medicare Program. Do you recognize what this is?
A. No.
Q. Do you know that in November of 2000 HCFA instructed its carriers not to use the Department of Justice data that were distributed in the September 8, 2000 program memorandum?
A. I know it now, but I didn't know it

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then.
Q. In the second paragraph it says that Congressional action may preclude the use of this alternative source of data.
Did Congressional action preclude the use of the DOJ data?
A. I believe it did.
Q. And do you recall having any conversations with Congress about why Congress took that action?
MS. YAVELBERG: Objection; form.
A. No.
Q. Do you know why Congress took that action?
A. No.
Q. Do you know if there was any lobbying or concern by other providers who would have been impacted by the program memorandum of September 8, 2000?
A. No.
Q. Ms. DeParle, when you were Administrator of HCFA did you ever have any

EXHIBIT AZ

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC [illegible]

February 13, 1998

The Honorable Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. DeParle:

As you may know, the Balanced Budget Act of 1997 included a provision reducing the Medicare payment for drugs to 95 percent of average wholesale price. The Congress adopted this approach instead of the Administration's proposal to pay for drugs on the basis of acquisition cost.

On January 9, your agency issued proposed regulations to implement the "Stark II" legislation. Included in the proposal (page 1694 of the Federal Register) is a discussion of discounts as a form of remuneration, which states that physicians must fully pass on to Medicare and other insurers the amount of any discount they receive on the purchase of drugs. "Discount" is not defined.

We are concerned that this proposal is intended to require physicians to bill Medicare for drugs at their acquisition cost. We would view any such attempt by HCFA to impose acquisition costs in direct conflict with Congressional intent and would strongly oppose such a measure. I would appreciate your clarifying HCFA's intent with regards to this matter as soon as possible.

Sincerely,

Bill Thomas
Chairman
Subcommittee on Health

Bill Archer
Chairman